

AMENDED IN SENATE MAY 1, 2003

AMENDED IN SENATE APRIL 21, 2003

SENATE BILL

No. 322

Introduced by Senator Ortiz

February 19, 2003

An act to add Sections 125118, 125119, 125120, 125121, and 125122 to the Health and Safety Code, relating to medical research.

LEGISLATIVE COUNSEL'S DIGEST

SB 322, as amended, Ortiz. Stem cell research proposals.

Existing law states the policy of the state that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation, shall be permitted and that full consideration of the ethical and medical implications of this research be given, and that research involving the derivation and use of these cells shall be reviewed by an approved institutional review board.

This bill would require the Director of the State Department of Health Services to establish a Human Stem Cell *Research* Review Council, to be comprised of specified members. This bill would require the council to develop guidelines for research involving the derivation or use of human *embryonic* stem cells in the state. The bill would provide that it is unprofessional conduct for any licensed health care provider to conduct research concerning human *embryonic* stem cells in a manner that does not comply with these guidelines. The bill would authorize the council to take specified actions if the council determines that a researcher is conducting research in a manner that is in conflict with the guidelines.

This bill would also impose specified reporting requirements on principal investigators conducting research projects concerning the derivation or use of human *embryonic* stem cells. The bill would require all research projects concerning this topic to be reviewed and approved by ~~a federally approved~~ an institutional review board *that is established in accordance with federal regulations*.

This bill would also require the council to report annually to the director and the Legislature concerning its activities.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. (a) The Legislature finds and declares all of the
2 following:

3 (1) Isolation of human *embryonic* stem cells represents a major
4 step forward in human biology and has generated much interest
5 among scientists and the public, particularly among patients and
6 their advocates regarding the benefits of human *embryonic* stem
7 cells and stem cell research.

8 (2) Because human *embryonic* stem cells can give rise to many
9 different types of cells, such as muscle cells, nerve cells, heart
10 cells, and others, they are enormously important to science and
11 hold great promise for advances in health care.

12 (3) Research using human *embryonic* stem cells may help
13 scientists generate cells and tissue that could be used for
14 transplantation and may someday be used as replacement cells and
15 tissue to treat many diseases and conditions, including Parkinson's
16 disease, spinal injury, stroke, burns, heart disease, diabetes, and
17 arthritis.

18 (4) Research involving human *embryonic* stem cells may also
19 improve understanding of the complex events that occur during
20 normal human development and what causes diseases and
21 conditions including birth defects and cancer, and may improve
22 the way new drugs are developed and tested for safety and efficacy.

23 (5) In view of the scientific and medical benefits that may result
24 from research using human *embryonic* stem cells, it is essential
25 that this research be supported and encouraged. However, in view
26 of the ethical, legal, and social issues relevant to human *embryonic*
27 stem cell research, it is essential that this research be subjected to

oversight more stringent than that associated with the traditional National Institutes of Health scientific peer review process.

(6) The National Institutes of Health currently has no comprehensive guidelines concerning the ethical, legal, and social issues involved with the derivation and use of human *embryonic* stem cells in medical research.

(b) Therefore, it is the intent of the Legislature to establish a state entity to develop guidelines for human *embryonic* stem cell research in California and to review research projects involving the derivation or use of human *embryonic* stem cells to ensure that these projects are conducted in an appropriate manner and comply with ethical and legal standards.

SEC. 2. Section 125118 is added to the Health and Safety Code, to read:

125118. (a) The director shall establish a Human Stem Cell Research Review Council.

(b) The council shall consist of 13 members, comprised as follows:

(1) Seven scientists with experience in biomedical research in the fields of cell differentiation, nuclear reprogramming, tissue formation and regeneration, stem cell biology, developmental biology, regenerative medicine, or related fields, who are not currently conducting, and have no plans to conduct, research involving human *embryonic* stem cells.

(2) Two medical ethicists.

(3) Two persons with backgrounds in legal issues involved with human *embryonic* stem cell research, in vitro fertilization, or family law as it applies to donation of embryos and oocytes.

(4) Two persons who are members or leaders of religious organizations.

SEC. 3. Section 125119 is added to the Health and Safety Code, to read:

125119. (a) The council shall develop guidelines for research involving the derivation or use of human *embryonic* stem cells in California and for review of research projects involving the derivation or use of human *embryonic* stem cells in California.

(b) In developing the guidelines specified in subdivision (a), the council may consider other applicable guidelines developed or in use in the United States and in other countries, including, but not limited to, the Guidelines for Research Using Human Pluripotent

1 Stem Cells developed by the National Institutes of Health and
2 published in August 2000, and corrected in November 2000.

3 SEC. 4. Section 125120 is added to the Health and Safety
4 Code, to read:

5 125120. All research projects involving the derivation or use
6 of human *embryonic* stem cells shall be reviewed and approved by
7 ~~a federally approved~~ *an* institutional review board *that is*
8 *established in accordance with federal regulations* prior to being
9 undertaken. Any ~~federally approved~~ *such* institutional review
10 board shall ensure that any project that it reviews meets and
11 complies with the guidelines developed by the council pursuant to
12 Section 125119.

13 SEC. 5. Section 125121 is added to the Health and Safety
14 Code, to read:

15 125121. (a) The principal investigator in any research
16 project involving the derivation or use of human *embryonic* stem
17 cells that has been reviewed and approved by ~~a federally approved~~
18 *an* institutional review board *that is established in accordance*
19 *with federal regulations* shall submit, or cause to be submitted, to
20 the council established pursuant to Section 125118, on a timetable
21 to be established by the council, progress reports on the research
22 that are sufficient to enable the council to determine that the
23 research continues to comply with the guidelines established by
24 the council.

25 (b) The conduct of research involving the derivation or use of
26 human *embryonic* stem cells in a manner that does not comply
27 with the guidelines established pursuant to Section 125119 by any
28 licensed health care provider shall constitute unprofessional
29 conduct.

30 (c) If the council determines that a researcher is conducting
31 research in a manner in conflict with the guidelines established
32 pursuant to Section 125119, it may take any of the following
33 actions:

- 34 (1) Request a modification in the research plan or design.
35 (2) Request that the research be discontinued.
36 (3) Request that funding for the research be discontinued.
37 (4) Refer any investigator or principal to an appropriate
38 licensing board.
39 (5) Refer the conduct to any law enforcement body, if
40 appropriate.



1 SEC. 6. Section 125122 is added to the Health and Safety
2 Code, to read:
3 125122. The council shall report annually to the director and
4 the Legislature on its actions, including the number of research
5 projects that it has reviewed and the status and disposition of those
6 projects.

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